

## DETAILED ACTION

### ***Claim Rejections - 35 USC § 103***

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 1, 3-4, 12-16, 22, and 24-25 are rejected under 35 U.S.C. 103(a) as being unpatentable over Lee (United States Patent Application Publication Number 2003/0139762) in view of Bleam (United States Patent Number 5,797,878).

Lee discloses a dilation catheter comprising an elongate catheter body with a lumen and a balloon (40) in communication with the lumen, the balloon comprising a working length (44) surrounded by proximal and distal regions, each of which comprises a taper-to-neck transition and a working length-to-taper transition (proximal taper 48 includes a proximal taper-to-neck transition near ref. 42, and a proximal working length-to-taper transition at ref. 40, similar transitions are found at distal taper 50). Lee discloses that the balloon is between 1.5 and 15 mm in diameter (paragraph [0020]). Lee also teaches that the tapers of the balloon should be smooth in order to allow the balloon to traverse stenoses ((paragraph [0005])), but Lee does not disclose specific radii of transition with respect to the balloon. However, Bleam discloses that smaller taper angles and longer taper lengths can reduce cross and recross forces in balloon catheters (col. 2, lines 12-22, and 60-67). Given Bleam's disclosure that smaller angles

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of taper and longer taper lengths minimize cross and recross forces, it would have been obvious to one of ordinary skill in the art at the time the invention was made to utilize larger radii of transition as well as decreased taper angles and increased taper lengths in a balloon sized as specified by Lee, in order to increase the smoothness of the taper even further and minimize cross and recross forces as much as possible. Furthermore, It would have been obvious to one having ordinary skill in the art at the time the invention was made to utilize transitional radii within the ranges listed in claims 1, 3-4, 22, and 24-25 for the balloon diameters specified, since it has been held that where the general conditions of a claim are disclosed in the prior art, discovering the optimum or workable ranges involves only routine skill in the art. In re Aller, 105 USPQ 233.

Regarding claims 12-13, Blead discloses the angles at the taper-to-neck and working length-to-taper transitions being equivalent (col. 6, lines 57-65), and discloses that the balloon ends 22 and 24 are symmetrical (col. 6, lines 23-31).

Regarding claims 14-16, Lee discloses the proximal and distal tapers being asymmetric, and the diameters along the taper being either constant or varied (paragraph [0031]). As such it would have been obvious to one of ordinary skill in the art at the time the invention was made to provide varying transitional radii amongst any of the 4 transitions to accommodate the various taper diameters.

Regarding claim 22, Lee further discloses inserting a dilation catheter through a conduit, inflating the balloon, deflating the balloon, and applying a force to the catheter to remove the balloon (paragraphs [0004] and [0005]).

***Response to Amendment***

Applicant's amendment fails to meet the requirements listed in 37 CFR 1.121(c) requiring that the status of every claim must be indicated after its claim number by using an identifier, such as "Original," or "Previously presented," etc. In the amendment filed November 24, 2009, claims 22, 24, and 25 lack an identifier.

***Response to Arguments***

Applicant's arguments filed November 24, 2009 have been fully considered but they are not persuasive.

Applicant argues that both the Lee and Bleam references fail to disclose a dilation catheter with a balloon having the transitional radii claimed. Examiner maintains the rejection on the grounds that it would have been obvious, in view of Lee and Bleam, to provide a balloon with larger transitional radii in order to create an overall smoother balloon, and minimize cross and re-cross forces, as disclosed by Bleam.

***Conclusion***

**THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not

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mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to BRIAN GRAHAM whose telephone number is (571)270-7484. The examiner can normally be reached on Monday - Friday 8:00 am-5:00 pm EST.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Todd Manahan can be reached on (571)272-4713. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

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/BJG/

March 25, 2010

/Todd E Manahan/

Supervisory Patent Examiner, Art Unit 3734